UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,307	01/07/2002	Stephen Kent	229752001400	2826

25227 7590 12/16/2003

MORRISON & FOERSTER LLP
1650 TYSONS BOULEVARD
SUITE 300
MCLEAN, VA 22102

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	15

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,307	KENT ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Office Action

Status of the Claims

1. Claims 1-38 are pending in the instant application. No preliminary claim amendments were present in the application.

35 U.S.C. § 120

2. If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. **If applicant desires priority based upon a National Stage filing, this information should also be referenced in the first sentence of the specification (i.e., This application is a National Stage entry of International Application No. PCT/CCPY/NNNNN, filed , 199N).**

37 C.F.R. § 1.98

3. The listing of references in the specification is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and M.P.E.P. § 609 ¶ A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited or considered by the examiner on a form PTO-892 or PTO-1449, they have not been considered.

35 U.S.C. § 112, Second Paragraph

4. Claim 38 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claim references an "agent" which is vague and indefinite since the salient characteristics of said agent are not readily manifest. It is not clear what other ingredients are present in addition to the claimed recombinant constructs and what form the agent takes. Appropriate correction and clarification are required.

35 U.S.C. § 101

5.The following is a quotation of 35 U.S.C. § 101 which reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

6.Claims 36 and 37 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. The claims contain improper process language. Refer to M.P.E.P. § 2173.05(q). *Ex parte Dunki*, 153 U.S.P.Q. 678 (Bd. App. 1967). *Clinical Products Ltd.* v. *Brenner*, 255 F.Supp. 131, 149 U.S.P.Q. 475 (D.D.C. 1966).

35 U.S.C. § 103(a)

7. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

9. Claims 1-8, 17-20, and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Paoletti *et al.* (1998) in view of Ramshaw *et al.* (1999). Paoletti and colleagues provide avipox viral vectors (e.g., TROVAC, ALVAC) encoding lentiviral (e.g., HIV, SIV) gene products (e.g., Gag, Pol, Env) that are suitable for inducing viral-specific immune responses. This teaching does not disclose the utilization a second nucleic acid encoding a cytokine that functions as an adjuvant. However, Ramshaw and colleagues provide recombinant viral vectors carrying a first nucleic acid encoding a viral immunogen (e.g., HIV-1) and a second nucleic acid encoding a cytokine adjuvant (e.g., IL-2, γ-IFN) that facilitates the immune response to the immunogen. Therefore, it would have

been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the expression vectors of Paoletti *et al.* (1998), to include a second nucleic acid encoding a cytokine adjuvant as taught by Ramshaw *et al.* (1999), since this would reasonably be expected to enhance the immune response to the HIV-1 antigen of interest. Both the motivation and a reasonable expectation of success were clearly present in the prior art.

35 U.S.C. § 112, First Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 9-16 and 21-37 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are all directed toward HIV vaccine compositions, methods of making said compositions, and attendant methods of use to prevent HIV transmission or provide a therapeutic response in HIV-infected individuals. The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance

presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The state-of-the-art relative to HIV vaccine development is replete with failure. The development of an efficacious HIV vaccine has proven to be arduous. There are a number of factors that have precluded the successful development of an HIV vaccine including some of the following: (I) a lack of understanding of the correlates of protective immunity; (ii) a lack of understanding of protective immunogens, suitable adjuvants, routes of administration, and immunization regimens; (iii) the quasispecies nature of HIV replication leads to immune escape and effete immune responses; and (iv) the lack of an adequate animal model in which to assess vaccine efficacy (Haynes *et al.*, 1996; Lee, 1997; Letvin, 1998; Burton and Moore, 1998; Johnston, 2000; Feinberg and Moore, 2002).

2) The disclosure fails to provide adequate guidance pertaining to the correlates of protective immunity. In order to assess the effectiveness of any given putative vaccine, the skilled artisan needs to know the specificity and titer of those immune responses that induce protection or provide some sort of therapeutic effect. However, to date these correlates are not known and the disclosure fails to provide any further illumination on the subject. Thus, the skilled artisan cannot reasonably ascertain if any given putative vaccine composition will be protective.

3) The disclosure fails to provide adequate guidance pertaining to suitable immunogens, adjuvants, routes of administration, and immunization regiments. Since the correlates of protective

immunity remain to be elucidated, the skilled artisan cannot begin to predict which form the immunogen of interest should take (i.e., whole inactivated virus; live attenuated virus; subunit immunogen; combination of multiple immunogens in various forms), the appropriate adjuvants to be included, suitable routes of administration, or suitable immunization regimens. The disclosure fails to provide any further illumination on the subject.

4) The disclosure fails to provide any working embodiments. While it was noted that the specification described challenge studies involving one of the claimed compositions and a macaque model, many of the parameters of this study were not clearly disclosed (i.e., challenge virus, inoculating dose, etc.). In any event, the macaque model is clearly not predictive of clinical efficacy due to the various genotypic and phenotypic differences between macaques, humans, and the lentiviruses that infect them.

Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Correspondence

12. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the

status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

12 December, 2003